

**REMARKS**

Applicants are proceeding from the Office Action mailed September 15, 2008. On March 16, 2009, Applicants timely filed a Notice of Appeal. On September 24, 2009, The PTO mailed an erroneous Notice of Abandonment to which Applicants responded on October 8, 2009, requesting the PTO to vacate such incorrect Notice of Abandonment. Filed with the present Reply are (1) an RCE, and (2) a petition for five (5) months extension of time, together with the requisite fees for the RCE and extension of time.

The claims in the application are now claims 1-9, 11-17, 21, 22 and 23, with new claim 22 corresponding to a revised form of claim 9 and new claim 23 being a method in Jepson form. Applicants believe and respectfully submit that the claims define novel and unobvious subject matter which is fully in conformance with §112, whereby allowance of the claims is warranted. Favorable reconsideration and allowance are therefore earnestly solicited.

Applicants do not understand the third paragraph on page 2 of the Office Action mailed September 15, 2008, regarding sequence requirements, and therefore the requirement is respectfully traversed.

A sequence listing is of record in the present application. SEQ ID NO: 1 appears on the first page of such sequence listing. With respect to claim 5, for example, which is illustrative for claims 6-7, 15-17 and 21, the modification that results in a modified SEB is set forth at the top of page 2, wherein the SEB sequence of SEQ ID NO: 1 is modified at

positions 226-229 with the replacement sequence Leu Phe Ala Ala. Accordingly, this is an appropriate manner to reference specific amino acid modifications to a reference sequence (SEQ ID NO: 1). No other identifying sequence is required. Applicants accordingly believe and respectfully submit that the sequence requirements have been fully met.

As best can be understood from the bottom paragraph on page 2 and the top paragraph on page 3 of the Office Action of September 15, 2008, the previous rejections based on the first and second paragraphs of §112 have been withdrawn.

Claims 1, 2, 3, 8, 9-13 and 18-20 have been provisionally rejected on the basis of obviousness-type double patenting over claims 1, 4 and 6-9 of copending Application No. 10/570,499. This rejection is again respectfully traversed for the reasons of record, respectfully repeated by reference.

Applicants accept that the conflicting claims are not identical, whereby statutory double patenting does not apply.

First, regardless of the points raised in the Office Action, it remains **in fact** that there can be no double patenting until claims have actually been patented. The claims in copending Application No. 10/570,499 have been rejected, and the rejection has been appealed. As the record now stands in the copending application, the PTO position is that such claims are not allowable; and, if the rejection is maintained, such claims will not become patented, wherefore there can be no double patenting in fact.

Accordingly, Applicants respectfully request that the double patenting rejection be held in abeyance. Nevertheless, Applicants hereby express a willingness to file a terminal disclaimer when other issues have been resolved.

Claims 1-3, 8-13 and 18-20 have been rejected under §102 as being anticipated by Sasaki. This rejection is respectfully traversed for the reasons of record, respectfully repeated by reference.

With reference to paragraph [0012] of Sasaki, it is seen that Sasaki gives too many alternatives for substitution at the 23 position for there to be a valid rejection based on §102. Sasaki does not put the reader of Sasaki in possession of the presently claimed subject matter.

For a reference to be properly anticipatory under §102, the reference must disclose each and every element of the claimed invention, *Eli Lilly and Co. v. Zenith Goldline Pharms., Inc.*, 81 USPQ2d 1324, 1328 (Fed. Cir. 2006), and those elements must be "arranged or combined in the same way as in the claim," *Net MoneyIN Inc. v. VeriSign Inc.*, 88 USPQ2d 1751, 1759 (FedCir. 2008), quoting from *Finisar Corp. v. DirectTV Group Inc.*, 86 USPQ2d 1609, 1618 (Fed. Cir. 2008). Applicants do not see that Sasaki meets the test for being properly anticipatory under §102 as required by the aforementioned case law.

Moreover, Applicants do not understand the bottom paragraph on page 5 of the Office Action. Applicants do not understand what Nishi has to do with a rejection based on Sasaki, and does not understand what the reference to Nishi has to do with what is commensurate in scope with Applicants' claims.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-4 and 9-11 have been rejected as anticipated under §102 by Nishi. This rejection is respectfully traversed for the reasons of records, respectfully repeated by reference.

As pointed out at the bottom of page 6 of the Applicants' specification, Nishi suggests that a major epitope recognized by an anti-SEB antibody in human serum is located at the C-terminal of SEB, and an antibody against such C-terminal region is a neutralizing antibody to SEB. The solution proposed by Nishi could only be expressed in an insoluble form, and therefore does not conform with what is inherently present in Applicants' claims. The Examiner says that the argument is not commensurate in scope with Applicants' claims, but Applicants respectfully maintain that their claims inherently define over Nishi.

Nevertheless, the claims are amended above to make explicit what Applicants believe was already in their claims. Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-3, 8-13 and 18-20 have been rejected under §102 as anticipated by Kappler. This rejection is respectfully traversed for the reasons of record, respectfully repeated by reference.

Applicants do not agree that the recitation "adapted for immunopathy" is a statement of intended use, but instead Applicants respectfully submit that it defines a characteristic

of the claimed subject matter and therefore defines in part what is being claimed rather than an intended use.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-21 have been rejected under §103 as obvious from Nishi in view of Sasaki and Kappler. This rejection is respectfully traversed for the reasons of record, respectfully repeated by reference, and for the additional reasons set forth below.

Based on the unsuccessful results of Nishi, it could not have been reasonably expected by the person of ordinary skill in the art that the Applicants would have been able to provide the results demonstrated in the present specification. This constitutes nonobvious subject matter. The claimed invention "yield[s more than] predictable results." [Ortho-McNeil v. Teva, Fed. Cir. 2009]

Applicants also respectfully submit that there are no reasons provided in the prior art which would have led the person of ordinary skill in the art at the time the present invention was made to have even tried (attempted) to combine the references as proposed.

Withdrawal of the rejection is in order and is respectfully requested.

Claim 21 has been substantially amended, and new claims 22 and 23 have been added. These claims define patentable subject matter for the reasons pointed out above, and

In re of Toshihiro NAKASHIMA et al  
Application No. 10/551,263  
Reply Accompanying RCE filed October 16, 2009

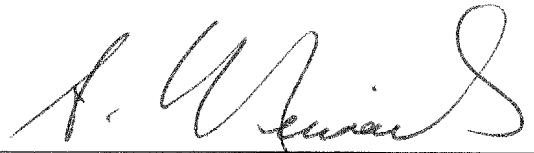
in addition call for additional subject matter which is not  
shown or made obvious by the prior art.

Favorable reconsideration and allowance are earnestly  
solicited.

Respectfully submitted,

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By

A handwritten signature in dark ink, appearing to read 'S. Neimark', written over a horizontal line.

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